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<p>(21) International Application Number: PCT/US97/02805</p> <p>(22) International Filing Date: 21 February 1997 (21.02.97)</p> <p>(30) Priority Data: 60/013,030 21 February 1996 (21.02.96) US</p> <p>(71) Applicant (for all designated States except US): SMITH & NEPHEW INC. [US/US]; 1450 Brooks Road, Memphis, TN 38116 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): CARLS, Thomas, A. [US/US]; 4992 Princeton, Memphis, TN 38117 (US). LACKEY, Jennifer, J. [US/US]; 3777 Northwood Drive, Memphis, TN 38111 (US). KELMAN, Dave [US/US]; 10306 W. Shrewsbury Run, Collierville, TN 38017 (US). MARTENS, Todd [US/US]; 6890 Amberly Grove, Cordova, TN 38018 (US).</p> <p>(74) Agents: KRIEGER, Paul, E. et al.; Pravel, Hewitt, Kimball & Krieger, 10th floor, 1177 West Loop South, Houston, TX 77027 (US).</p>		<p>(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>
<p>(54) Title: TRIAL WEDGES WITH MAGNETIC ATTACHMENTS</p> <p>(57) Abstract</p> <p>An orthopaedic surgical trial instrument for use in joint replacement (e.g., knee, hip, shoulder) surgery includes a trial body (11) of selected size and shape that can receive trial shims or wedges (20) of differing size and shape so that a surgeon can construct a trial during surgery that closely fits a patient's anatomy. Magnetic members (29) aid in holding a selected wedge to a selected trial. Corresponding projections (27, 11B) and recesses (11A, 28) prevent rotation of wedges (20) with respect to the selected trial (11).</p> <div data-bbox="958 1113 1429 1701"> </div>		

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PATENT APPLICATION

TITLE OF THE INVENTION

"TRIAL WEDGES WITH MAGNETIC ATTACHMENTS "

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CROSS-REFERENCE TO RELATED APPLICATIONS

Priority of U.S. Provisional Patent Application Serial No. 60/013,030, filed February 21, 1996, incorporated herein by reference, is hereby claimed.

15 STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable

REFERENCE TO A "MICROFICHE APPENDIX"

Not applicable

BACKGROUND OF THE INVENTION

20 1. Field of the Invention

The present invention relates to orthopaedic surgical instruments such as surgical trials, and more particularly a surgical trial instrument for use in joint replacement surgery (e.g., knee, hip, shoulder), wherein an improved trial wedge includes a magnetic member inserted into the trial wedge so that it can securely yet
25 removably be attached to another part such as a trial femoral or tibial component, a cutting block, or like orthopaedic instruments.

2. General Background of the Invention

During total knee replacement surgery, the surgeon prepares the patient s proximal tibia to receive a tibial implant. The surgeon also prepares the patients
30 distal femur of the patient with surgical cuts so that it can receive a femoral

component. It is often desirable to first attach the femoral component to the patient's distal femur before placing the tibial prosthesis component. One of the reasons for placing the tibial component after the femoral component is that the tibial prosthesis uses a polymeric liner for articulating with a smooth polished metallic surface on the femoral component.

Before placing the actual final tibial prosthesis and femoral prosthesis, the surgeon generally uses a number of trial prostheses of different sizes and configurations as well as different polymeric liner inserts in a search for the best fit.

When trial prostheses are used, trial wedges are sometimes also used to evaluate the amount of augmentation necessary in the final femoral and tibial prosthesis components. Trial wedges are also used to help stabilize the cutting blocks and the femoral and tibial trial prostheses as well as other instruments used during the total knee replacement surgery.

Presently, trial wedges are attached to trial components and the cutting blocks with bone wax, screws or snap rings. However, other than the bone wax, these other attachments limit the placement options of the trial wedge. The use of bone wax presents problems of its own in that it can be somewhat difficult to work with and needs to be removed prior to implantation of the final prosthesis.

U.S. Patent 5,425,763 discloses a magnet arrangement for fastening prostheses, in particular epitheses, such as for example artificial ears and the like. In a magnet arrangement for the fastening of prostheses, in which a magnet can be inserted into a prosthesis and a magnet to be implanted or to be fastened on an implant are provided. There is also provided, to achieve a more reliable mounting during a displacement movement of the prosthesis, a guide by which the two magnets are guided one on the other in such a manner that they are displaceable telescopically relative to one another in the holding direction of the prosthesis.

An artificial joint with magnetic attraction or repulsion is the subject of U.S. Patent 4,024,588. The 588 patent discloses an artificial joint for implantation into the living body. It comprises a head portion adapted to be

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anchored in one bone of the body and a socket portion adapted to be anchored in another bone. One of the head and socket portions includes a permanent magnet and the other portion either a magnetizable element or another permanent magnet. The two interacting magnetic elements may be polarized for either attraction or repulsion. The head and socket portions are shaped to permit translatory movement relative to each other in addition to rotary movements of the head portion about at least one axis of rotation.

BRIEF SUMMARY OF THE INVENTION

The present invention solves these problems and short comings by providing a trial prosthesis body that can be augmented with trial wedges or shims that have at least one magnet inserted into the wedge so that it can be magnetically attached to selected trial components, a broach or like orthopaedic instrumentation. At least one magnet can be placed into the trial wedge. The magnet type, size and location can be determined by the size and shape of the trial wedge. A pair of magnets can be inserted on respective sides of a wedge so that a wedge can be flipped over for use medially or laterally.

Thus, the present invention provides a magnetic orthopaedic trial apparatus that enables trial wedges to be easily attached to trial components (e.g., femoral components, tibial components, hip replacement components), cutting blocks or other instruments that are used during total knee or total hip replacement surgery.

The present invention provides a surgical orthopaedic joint replacement trial instrument that includes a trial body having a stem portion that fits a patients intramedullary canal. A plurality of trial wedges removably attach to the trial body enabling a surgeon to vary the size and shape of the trial body such as during the fitting of a trial to a patients femur or tibia tissue.

At least some of the trial wedges have opposed surfaces that are generally parallel to one another. A magnetic member holds a selected of the trial wedges and the trial body together.

In the preferred embodiment, the magnetic member is a magnet that is embedded within each trial wedge.

In the preferred embodiment, at least some of the trial wedges have opposed surfaces that define an acute angle.

The trial body preferably has at least one flat surface that receives a correspondingly flat surface of a trial wedge.

5 The trial body can have two spaced apart surfaces that enable a surgeon to attach two trial wedges simultaneously to the respective spaced apart surfaces of the trial body.

Each of the spaced apart surfaces is preferably flat. At least some of the wedges are shaped to stack one upon the other. In this fashion, the surgeon can
10 place a first wedge on one of the flat surfaces of the trial body. The surgeon can then place another trial wedge on a second flat surface of the trial body. Alternatively, the surgeon can place an additional trial wedge on top of one of the previously placed trial wedges so that at least two of the trial wedges are stacked one upon the other at one of the flat surfaces of the trial body.

15 In the preferred embodiment, the trial body and at least some of the wedges are embossed with correspondingly shaped embossed surfaces to prevent rotation once a wedge is attached to a trial body.

The trial body and at least some of the wedges have corresponding interlocking portions such as, for example, a cylindrically-shaped socket on the
20 trial body and a correspondingly shaped cylindrical projection on the trial wedge.

The interlocking portions can include interlocking socket and projecting portions that are correspondingly shaped.

In the preferred embodiment, a collection of trial wedges are provided having differing thicknesses and differing shapes.

25 The trial body can have an articulating surface portion for articulating with a corresponding articulating surface of another orthopaedic prosthetic component.

In one embodiment, the surgical orthopaedic joint replacement trial is in the form of a tibial trial having a stem, a tibial tray, and trial wedges that are fixed to distal surfaces of the tray portion of the trial body.

30 In another embodiment, the trial instrument is in the form of a femoral trial

component having trial wedges that affix to distal non-articulating surfaces of the trial body and to the posterior condylar non-articulating surface portions of the trial body. Further, some trial wedges can be sized and shaped to provided surfaces that simultaneously abut both the distal non-articulating surface and the
5 condylar non-articulating surface of the trial body.

Yet another embodiment provides a broach that is in the shape of a trial hip prosthesis that is sized and shaped to fit the patients proximal femur during hip joint replacement surgery.

The trial hip replacement prosthesis is in the form of a broach having a
10 proximal end that removably accepts a trial neck member wherein a plurality of the removable trial members provide different neck geometry, enabling the surgeon to vary the configuration of a trial that fits the patients proximal femur during hip joint replacement surgery.

BRIEF DESCRIPTION OF THE DRAWINGS

15 For a further understanding of the nature, objects, and advantages of the present invention, reference should be had to the following detailed description, read in conjunction with the following drawings, wherein like reference numerals denote like elements and wherein:

For a further understanding of the nature and objects of the present
20 invention, reference should be had to the following detailed description, taken in conjunction with the accompanying drawings, in which like parts are given like numerals, and wherein:

FIGURE 1 is a partial side view of the first embodiment of the apparatus of the present invention showing a trial femoral component;

25 FIGURE 2 is a partial side view of the first embodiment of the apparatus of the present invention showing a trial femoral component with a trial wedge attached;

FIGURE 3 is a partial side view of the first embodiment of the apparatus of the present invention showing a trial femoral component with a pair of stacked
30 trial wedges attached;

FIGURE 4 is a partial side view of the first embodiment of the apparatus of the present invention showing a trial femoral component with a pair of stacked trial wedges attached;

5 FIGURE 5 is a perspective exploded view of the first embodiment of the apparatus of the present invention;

FIGURE 6 is a fragmentary perspective view of the first embodiment of the apparatus of the present invention showing the stacking tray portion thereof;

FIGURE 7 is a perspective view of the first embodiment of the apparatus of the present invention;

10 FIGURE 8 is a fragmentary top view of the first embodiment of the apparatus of the present invention illustrating a trial wedge that can be attached to the femoral trial body of Figures 1-4;

FIGURE 9 is a fragmentary elevational view taken along lines 9-9 of Figure 8;

15 FIGURE 10 is a sectional view taken along lines 10-10 of Figure 8;

FIGURE 11 is a fragmentary top view of the first embodiment of the apparatus of the present invention illustrating a trial wedge that can be attached to the trial body of Figures 1-4;

FIGURE 12 is a side elevational view taken along lines 12-12 of Figure 11;

20 FIGURE 13 is an end, elevational view taken along lines 13-13 of Figure 11;

FIGURE 14 is a fragmentary top view of the first embodiment of the apparatus of the present invention illustrating a trial wedge that can be attached to the femoral trial body of Figures 1-4;

25 FIGURE 15 is an end, elevational view taken along lines 15-15 of Figure 14;

FIGURE 15A is a fragmentary end view of the first embodiment of the apparatus of the present invention illustrating a trial wedge that can be attached to the femoral trial body of Figures 1-4;

30 FIGURE 16 is a top view of the first embodiment of the apparatus of the

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present invention illustrating a trial wedge that can be attached to the femoral trial body of Figures 1-4;

FIGURE 17 is a partial perspective view of the first embodiment of the apparatus of the present invention illustrating the attachment of trial wedges thereto at the posterior mount articulating surfaces thereof;

FIGURE 18 is a perspective exploded view of a second embodiment of the apparatus of the present invention in the form of a tibial trial;

FIGURE 19 is a fragmentary perspective view of the second embodiment of the apparatus of the present invention showing the tibial tray;

FIGURE 20 is a fragmentary view of the second embodiment of the apparatus of the present invention illustrating the distal surface of the tibial trial body;

FIGURE 21 is an end view taken along lines 21-21 of Figure 20;

FIGURE 22 is an end view taken along lines 22-22 of Figure 20;

FIGURE 23 is a fragmentary top view of the second embodiment of the apparatus of the present invention illustrating one of the trial wedge portions thereof;

FIGURE 24 is an end view taken along lines 24-24 of Figure 23;

FIGURE 25 is a side view taken along lines 25-25 of Figure 23;

FIGURE 25A is a side view of a trial wedge portion of the second embodiment of the apparatus of the present invention;

FIGURE 26 is a sectional view taken along lines 26-26 of Figure 23;

FIGURE 27 is a fragmentary top view of the second embodiment of the apparatus of the present invention illustrating one of the trial wedge portions thereof;

FIGURE 28 is an end view taken along lines 28-28 of Figure 27;

FIGURE 28A is an end view of a trial wedge portion of the second embodiment of the apparatus of the present invention;

FIGURE 29 is a side taken along lines 29-29 of Figure 27;

FIGURE 30 is a plane, fragmentary top view of the second embodiment of

the apparatus of the present invention illustrating one of the trial wedge portions thereof;

FIGURE 31 is an end view taken along lines 31-31 of Figure 30;

FIGURE 32 is an elevational view of the second embodiment of the apparatus of the present invention;

FIGURE 33 is an elevational view of the second embodiment of the apparatus of the present invention;

FIGURE 34 is a perspective view of the second embodiment of the apparatus of the present invention illustrating its use with a tibial wedge cutting block;

FIGURE 35 is a partial perspective view of the second embodiment of the apparatus of the present invention illustrating the tibial wedge cutting block portion thereof and its handle;

FIGURE 36 is a side elevational view of the second embodiment of the apparatus of the present invention shown attached to a tibial wedge cutting guide and its handle;

FIGURE 37 is a side view of a third embodiment of the apparatus of the present invention;

FIGURE 38 is an exploded side view of the third embodiment of the apparatus of the present invention;

FIGURE 39 is a side view of the third embodiment of the apparatus of the present invention with the removable neck portion removed;

FIGURE 40 is a partial perspective view of the third embodiment of the apparatus of the present invention;

FIGURE 41 is a sectional view taken along lines 41-41 of Figure 37;

FIGURE 42 is a sectional view taken along lines 42-42 of Figure 37;

FIGURE 43 is a perspective view of a fourth embodiment of the apparatus of the present invention; and

FIGURE 44 is a side view of the fourth embodiment of the apparatus of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Figures 1-4 show generally the preferred embodiment of the apparatus of the present invention designated by the numeral 10A in Figures 2-4, 5, and 7.

5 Femoral trial prosthesis 10A includes a trial body 11 that is generally of a size and shape that corresponds to the shape of a final femoral prosthesis. A surgeon can use one or more such trials to obtain a correct fit. Using the apparatus of the present invention and the method of the present invention, wedges can be added to the trial body 11 in order to compensate for bone loss and/or bone defect.

10 Trial body 11 includes a distal articulating surface 12, an anterior articulating surface 13, and a posterior articulating surface 14 in the form of a pair of space-apart condylar portions. A plurality of five non-articulating surfaces are also provided on trial body 11 including flat non-articulating surfaces 15, 16, 17, 18, and 19. These five surfaces 15-19 correspond in size, shape, and positioning to surgical cuts that are made by a surgeon on a patients distal femur. Trial body
15 11 has sockets 11A, 11B that are receptive of projecting portions of trial wedges 20, 30.

The method and apparatus of the present invention provides a plurality of trial wedges, each of a different size and shape that can be added to the trial body 11 depending upon the amount of bone tissue loss that the surgeon finds on a
20 particular patient during knee joint replacement surgical procedure. In Figures 2, 3, 5, 7, and 11-13, trial wedge 20 is shown. Figure 2 shows an addition of trial wedge 20 to trial body 11 wherein the trial wedge 20 mates with flat non-articulating surfaces 16, 17, 18 of trial body 11. In Figures 11-13, trial wedge 20 is shown more particularly.

25 Trial wedge 20 has a flat proximal surface 21, beveled surfaces 22, 24 and flat distal surface 23. A pair of side walls 25, 26 are provided that extend between the distal surface 23 and proximal surface 21. A cylindrical boss or projection 27 is provided on distal surface 23. The cylindrical projection 27 mates with a correspondingly-shaped cylindrical recess or socket 11A, 11B on trial body 11.
30 A cylindrical opening 28 in wedge 20 accepts a correspondingly-shaped magnetic

member 29 and adhesive. This magnetic member 29 enables trial wedge 20 to form a connection with trial body 11. The trial body 11 can be of steel, enabling magnetic member 29 to attach thereto. Alternatively, a steel bushing can be embedded in trial body 11 if the trial body 11 is a casting of plastic or a metal alloy that is not ferromagnetic.

In Figure 3, two trial wedges 20 illustrate that further thickness can be provided to trial body 11 by stacking the two wedges 20 as shown. In Figure 4, two differing wedges 20 and 30 are shown stacked upon the non-articulating surfaces 16, 17, 18, 19. The wedge 20 receives trial wedge 30, stacked thereon as shown in Figure 4.

The construction of trial wedge 30 is shown more particularly in Figures 8-10. The trial wedge 30 includes a flat distal surface 31 and a flat posterior surface 32. A pair of spaced apart side walls 33A, 34A extend from flat distal surface 31 to flat proximal surface 38. The trial wedge 30 has an anterior end 35 that is somewhat pointed, being defined by angled side walls 33 and 34 and beveled distal surface 36 and proximal surface 38. Flat surface 39 is provided on trial wedge 30 intersecting surface 38 at right angles. The surface 32 registers against a posterior non-articulating surface 19 of trial body 11 as shown in Figure 4. Socket 28 can receive a projecting portion of another trial wedge such as the projecting portion 37 of trial wedge 30 (see Figure 4).

In Figures 5-7, an additional stacking member is shown in the form of stacking tray 100. The tray 100 has a stem portion 101 with a threaded end 102. This enables modular stem extensions to be threadably attached to the stacking tray 100 at threaded end 102. The tray 100 has a distal surface 104 that carries a pair of spaced apart cylindrically-shaped projections 105, 106. These projections 105, 106 register in correspondingly-shaped sockets 11A, 11B of femoral trial 11.

The tray 100 has an inclined plate 103 that forms an obtuse angle with a pair of spaced apart distal 107, 108. The distal plates 107, 108 register against the flat non-articulating surface 17 of trial body 11. The inclined plate 103 registers against flat non-articulating surface 16 of trial body 11. This configuration can be

seen in Figures 5 and 7.

The proximal surface 109 of tray 100 has a pair of spaced apart sockets 110, 111. The sockets 110, 111 receive the projecting cylindrically-shaped portion found on the distal surface of each trial wedge 20, 30. The proximal surface 109 of tray 100 has receptacle portions 113, 114 that are sized and shaped to receive a selected trial wedge 20 or 30. This enables a selected trial wedge 20 or 30 to be nested upon the proximal 109 surface of tray 100 as shown in Figure 7, while the tray 100 simultaneously nests upon the trial body 11.

In Figures 14-17, additional trial wedges are shown that can be attached to the posterior non-articulating surface 19 of femoral trial 11. These include trial wedge 115 that is of a first thickness as shown in Figure 15. A wedge 115 can be thicker as shown by the trial wedge 115A of Figure 15A. Further, the trial wedge 115 can be shortened as shown in Figure 16, the shorter trial wedge being designated by the numeral 116.

Each of the trial wedges 115, 115A, 116, have upper and lower generally opposed, parallel surfaces 117, 118. The surface 117 carries a projecting peg 119 that registers in a socket 120 on trial body 11 at non-articulating flat surface 19. A magnetic member 29 is embedded within each trial wedge 115, 115A, 116 as shown in Figures 14-16. Thus, the overall shape and configuration of each of the trial wedges 115, 115A, and 116 are substantially the same, the difference being in the increased thickness of the wedge 115A compared to the wedge 115 and the increased length of the wedge 115 when compared to the wedge 116.

A magnetic bushing 121 can be attached to each of the receptacles 113, 114 of tray 100. Similarly, magnetic bushings can be embedded in the femoral trial 11. This embedding of a magnetic member within the trial 11, or tray 100, or a selected other trial or instrument body enables the present invention to be used when the receiving part, trial, or instrument body is of plastic, an alloy, or other material that is not ferromagnetic.

Figures 18-19 show a second embodiment of the apparatus of the present invention designated generally by the numeral 10B in Figure 18. The embodiment

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of Figures 18 and 19 shows a tibial trial. The tibial trial includes a trial body tray 41 having a flat distal surface 42 that includes spaced apart flat surface areas 43, 44 to which magnetic trial wedges can be attached. A flat proximal surface 45 is provided that can receive a polymeric liner 52 (see Figures 32, 33).

5 Stem 46 extends from distal surface 42 at angles thereto. The stem 46 can have a threaded portion 47 for attaching a modular stem extension thereto when the surgeon is attempting to obtain a proper fit with the patients proximal tibia during knee joint replacement surgery.

10 Trial body 41 has a curved peripheral portion 48 that includes a socket 49 for receiving instrumentation such as cutting block 93 and its handle 94 (see Figures 34-36). Peripheral wall portions 50, 51 can be used to form attachments with polymeric liner 52 such as by means of a dovetailed-type connection. A plurality of projecting portions 53, 54 are provided respectively to the surface areas 43, 44 that will receive trial wedges during use. V-shaped slot 55 can be
15 used to accommodate other orthopaedic surgical instrumentation such as a V-shaped punch.

 Trial wedges 56 and 56A (see Figures 23-25A) can be attached to either selected surface 43 or 44. The trial wedges 56 and 56A are configured so that the same trial wedge 56 or 56A can be placed on either the medial or lateral side of
20 tray 41 by simply turning the trial wedge 56 or 56A over.

 Trial wedges 56 and 56A are shown more particularly in Figures 23-25, and 25A. The difference between the trial wedges 56 and 56A is the thickness, as shown in comparison in Figures 25 and 25A, the wedge 56A being thinner. Wedge 56 has a proximal surface 57 and a distal surface 58. A plurality of
25 recesses 59 are sized and shaped to fit on and conform to the projections 53, 54 of trial body 51 upon alignment. This provides a mechanical connection that prevents rotation between a selected trial wedge such as 56 or 56A and the tray 41. Cutouts 60, 61 are provided for forming a connection with a raised wall portion 42A at the periphery of flat distal surface 42 of tray 41.

30 The recess 60 is defined by intersecting shoulders 62 and 63. The cutout

61 is defined by intersecting shoulders 64 and 65. Each wedge 56, 56A has a peripheral curved surface 66 and a flat surface 67. Cutout 68 accommodates slot 55 as shown in Figures 18 and 20. The trial wedges 56 and 56A have flat surfaces 57, 58 that are opposed and generally parallel. This differs from the trial wedges 5 69, 69A of Figures 27-29 and 28A and the trial wedge 84 of Figures 30-31 that have opposed surfaces forming an acute angle.

Trial wedge 69 has a proximal surface 70, a distal surface 71, and a curved surface 79. A plurality of recesses 72 conform to the projecting portions 53, 54 of trial body 41. These recesses 72 in combination with the projections 53, 54 10 form a non-rotational connection between the selected trial wedge 69 or 69A and the trial body 41. Rotation is also discouraged between the wedges 69 and 69A with respect to the trial body 41 in the form of cutouts 73, 74. The cutout 73 is defined by shoulder 75, 76. The cutout 73 is defined by shoulders 77, 78. The trial wedges 69 and 69A are reversible, being applicable to either the medial or 15 lateral side of trial body 41 by simply turning the trial wedge 69 or 69A over.

A peripheral wall portion 42A on the distal surface 42 of trial body tray 41 connects with a cutout 73 or 74 upon assembly of the selected trial wedge 69 or 69A to the trial tray 41 as shown in Figure 18. Flat surface 80 extends along one side of each trial wedge 69, 69A. Cutout 81 accommodates slot 55. Curved arrow 20 82 in Figure 28 defines an angle formed by proximal surface 70 and distal surface 71. In Figure 28A, curved arrow 83 defines the angle between surfaces 70 and 71. The angles 82 and 83 can differ so that the surgeon is provided with multiple trial wedges having differing angular orientations between the proximal 70 and distal 71 surfaces.

25 In Figures 30-31, yet another trial wedge is shown, designated by the numeral 84. Trial wedge 84 has a proximal surface 85, a distal surface 86, a peripheral curved surface 90, and a flat surface 91. A plurality of recesses 87 are provided that are sized and shaped to conform to the projecting portions 53 and 54 of trial body 41. Cutouts 88 and 89 register with the raised wall portion 42A of 30 flat distal surface 42. The combination of the engagement of a selected cutout 88

or 89 with raised wall 42A and the connection between projecting portion 53 and 54 with recesses 87 forms a non-rotational connection between trial wedge 84 and trial body 11. Flat surface 91 forms one side of trial wedge 84 that is opposite curved surface 90. Trial wedge 84 is much smaller than the trial wedges 56, 56A, 69, 69A.

In each of the trial wedges of Figures 23-25, 25A, 26-29, 28A, 30-31, a pair of opposed magnetic members M are embedded in the trial wedge at both the proximal and distal surfaces thereof as shown in the drawings. This enables the magnetic member to form a connection with tray 41 notwithstanding that the trial wedge is placed on either the medial or lateral side of the trial tray 41. The trial tray 41 is preferably of a steel construction so that magnetics M attach the selected trial wedge thereto with magnetism.

In Figures 32 and 33, trial wedges of differing configuration are shown attached to the trial body 41. In Figure 32, trial wedges 69 and 69A are shown attached to the distal surface 42 of trial body 41. In Figure 33, trial wedges 56 and 56A are shown attached to the distal surface 42 of trial body 41.

Figures 34-36 show the attachment of a cutting block 93 to trial body tray 41 at its socket opening 49. A handle 94 forms a connection with cutting block 93. An extreme end portion 95 of handle 94 has a detent locking member 99 that forms a connection with a correspondingly shaped recess that is inside of socket opening 49. A release button 98 can be used to attach or disengage handle 94 from trial body 41. The cutting block 93 provides a pair of opposed cutting surfaces 96, 96A, 97, and 97A that enable a surgeon to guide a flat cutting blade or cutting saw by engaging the selected surface 96, 96A, 97, or 97A with such a saw or blade. This enables the surgeon to first place the trial body 41 on the patients proximal tibia and then make cuts using the surfaces 96, 96A, 97, or 97A that correspond to the shape of a particular trial wedge such as 56, 56A, 69, or 69A.

In Figures 37-42, a third embodiment of the apparatus of the present invention is shown, designated generally by the numeral 10C. Hip joint replacement trial 10C includes a broach member 130 having a proximal end 131

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and a tapered distal end 133. The tapered distal end 133 communicates with a generally conically-shaped stem 132. The stem 132 communicates with a broach or rasp section 134.

Removable neck trial member 135 has a frustoconical ball connector 136 that can receive a prosthetic femoral head ball forming, for example, a taper lock or morse taper connection therewith. A magnetic member (or members) can be used to attached a femoral head trial to a removable neck trial member 135. In such a case, the connector 136 free end could carry a magnetic member as could the correspondingly shaped socket of a trial femoral head. Removable neck member 135 has a socket 137 that receives a projecting portion 138 of broach member 130. The projecting portion 138 can also form a connection with a broach handle. Removable neck member 135 also has a rectangular section 143 that corresponds in size and shape to the rectangular slot 139 at proximal end 131 of broach member 130.

Upon assembly, the rectangular section 143 of removable neck section 135 fits into and closely conforms to slot 139 of broach member 130. Simultaneously, the projecting portion 138 of broach member 130 conforms to and occupies cylindrically-shaped socket 137 of removable neck section 135. This connection is illustrated by the arrows 144 in Figure 38. The rectangular slot 139 has a flat surface portion 142 that forms a magnetic connection with magnet 140 that is embedded in socket 141 of removable neck section 135. In order to form a magnetic connection between the removable neck section 135 and broach member 130, the magnetic member 140 that is permanently attached to removable neck member 135 at opening 141 is placed in connection with broach 130, as shown by arrows 144. The broach 130 can be of a metallic construction such as surgical steel. Alternatively, the flat surface 142 of slot 139 can carry an embedded steel bushing if the broach 130 is not of a steel construction.

The rasp section 135 can carry a plurality of teeth for cutting and rasping the intramedullary canal of a patients proximal femur during hip replacement surgery. Because the removable neck section 135 can be separated from broach

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130, this allows the surgeon to mix broach members 130 of different sizes and/or different configurations with removable neck members 135 of different sizes and/or of different configurations.

Figures 43-44 illustrate a fourth embodiment of the apparatus of the present invention, designated generally by the numeral 10D. Cutting block 10D is a femoral cutting block that includes block body 145 having anterior flange 148, distal surface 146, and posterior paddles 149, 150. Trial wedges as shown in Figures 8-16 can be added to the cutting block body 145 at distal surface 146 or at the posterior surface 147 of either paddle 149, 150. This enables a surgeon to use any of the aforescribed trial wedges (such as wedges 20, 115 shown in Figures 43-44) to be added to the trial body to custom fit a patients distal femur.

The following is a list of suitable parts and materials for the various elements of the preferred embodiment of the present invention.

PARTS LIST

15	Part Number	Description
	F	femur
	M	magnetic member
	10A	femoral trial prosthesis
	10B	tibial trial prosthesis
20	10C	hip joint trial prosthesis
	10D	cutting block
	11	trial body
	11A	socket
	11B	socket
25	12	distal articulating surface
	13	anterior articulating surface
	14	posterior articulating surface
	15	flat non-articulating surface
	16	flat non-articulating surface
30	17	flat non-articulating surface

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	18	flat non-articulating surface
	19	flat non-articulating surface
	20	trial wedge
	21	proximal flat surface
5	22	beveled surface
	23	distal flat surface
	24	beveled surface
	25	side wall
	26	side wall
10	27	cylindrical projection
	28	cylindrical opening
	29	magnetic member
	30	trial wedge
	31	flat distal surface
15	32	flat posterior surface
	33	angled side wall
	33A	side wall
	34	angled side wall
	34A	side wall
20	35	anterior end
	36	beveled distal surface
	37	projecting portion
	38	flat proximal surface
	39	flat surface
25	40	socket
	41	trial body tray
	42	flat distal surface
	42A	raised wall
	43	flat surface area
30	44	flat surface area

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	45	flat proximal surface
	46	stem
	47	threaded portion
	48	curved portion
5	49	socket
	50	peripheral wall
	51	peripheral wall
	52	polymeric liner
	53	projecting portion
10	54	projecting portion
	55	V-shaped slot
	56	trial wedge
	56A	trial wedge
	57	proximal surface
15	58	distal surface
	59	recess
	60	cutout
	61	cutout
	62	shoulder
20	63	shoulder
	64	shoulder
	65	shoulder
	66	curved surface
	67	flat surface
25	68	cutout
	69	trial wedge
	69A	trial wedge
	70	proximal surface
	71	distal surface
30	72	recess

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	73	cutout
	74	cutout
	75	shoulder
	76	shoulder
5	77	shoulder
	78	shoulder
	79	curved surface
	80	flat surface
	81	cutout
10	82	curved arrow
	83	curved arrow
	84	trial wedge
	85	proximal surface
	86	distal surface
15	87	recess
	88	cutout
	89	cutout
	90	curved surface
	91	flat surface
20	92	cutout
	93	cutting block
	94	handle
	95	connecting end portion
	96	cutting guide surface
25	96A	cutting guide surface
	97	cutting guide surface
	97A	cutting guide surface
	98	release button
	99	openings
30	100	tray

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	101	stem
	102	threaded portion
	103	inclined plate
	104	distal surface
5	105	projection
	106	projection
	107	distal plate
	108	distal plate
	109	proximal surface
10	110	socket
	111	socket
	112	proximal inclined surface
	113	receptacle
	114	receptacle
15	115	trial wedge
	115A	trial wedge
	116	trial wedge
	117	surface
	118	surface
20	119	peg
	120	socket
	130	broach
	131	proximal end
	132	conical stem
25	133	tapered distal end
	134	rasp section
	135	removable neck member
	136	frustoconical ball connector
	137	socket
30	138	projecting portion

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	139	rectangular slot
	140	magnetic member
	141	socket
	142	flat surface
5	143	rectangular section
	144	arrow
	145	cutting block
	146	distal surface
	147	posterior condylar surface
10	148	anterior flange
	149	paddle
	150	paddle

Because many varying and different embodiments may be made within the scope of the inventive concept herein taught, and because many modifications may be made in the embodiments herein detailed in accordance with the descriptive requirement of the law, it is to be understood that the details herein are to be interpreted as illustrative and not in a limiting sense.

CLAIMS

- 1 1. A surgical orthopaedic joint replacement trial instrument comprising:
2 a) a trial body that fits an end portion of a patients leg bone;
3 b) a plurality of trial wedge elements that removably affix to the
4 trial body, enabling a surgeon to vary the size and shape of the trial body;
5 c) at least some of the trial wedges having opposed surfaces that
6 are generally parallel; and
7 d) a magnetic member that holds a selected trial wedge and the
8 trial body together.
- 1 2. The surgical orthopaedic joint replacement of claim 1 wherein the
2 magnetic member is a magnet embedded within each trial wedge.
- 1 3. The surgical orthopaedic joint replacement of claim 1 wherein at
2 least some of the trial wedges have opposed surfaces that define an acute angle.
- 1 4. The surgical orthopaedic joint replacement of claim 1 wherein the
2 trial body has a flat surface that receives the trial wedges.
- 1 5. The surgical orthopaedic joint replacement of claim 1 wherein the
2 trial body has two spaced apart surfaces that enable a surgeon to attach two trial
3 wedges to the respective spaced apart surfaces.
- 1 6. The surgical orthopaedic joint replacement of claim 5 wherein each
2 of the spaced apart surfaces is generally flat.
- 1 7. The surgical orthopaedic joint replacement of claim 1 wherein at
2 least some of the wedges are shaped to stack one upon another.

1 8. The surgical orthopaedic joint replacement of claim 1 wherein the
2 trial body and at least some wedges are embossed to prevent rotation once a wedge
3 is attached to the trial body.

1 9. The surgical orthopaedic joint replacement of claim 1 wherein the
2 trial body and at least some wedges have corresponding interlocking portions.

1 10. The surgical orthopaedic joint replacement of claim 9 wherein the
2 interlocking portions comprise interlocking socket and projecting portions.

1 11. The surgical orthopaedic joint replacement of claim 1 wherein the
2 trial wedges have differing thicknesses.

1 12. The surgical orthopaedic joint replacement of claim 1 wherein the
2 trial body has an articulating surface portion for articulating with an articulating
3 surface of another orthopaedic prosthetic component.

1 13. A surgical orthopaedic joint replacement trial comprising:
2 a) a trial body having a stem portion that fits a patients
3 intramedullary canal, the trial body having a pair of spaced apart, flat non-
4 articulating surface portions;
5 b) a plurality of trial wedges that removably affix to the trial
6 body enabling a surgeon to vary the size and shape of the trial body;
7 c) at least some of the trial wedges having opposed surfaces; and
8 d) a magnetic member that enables a selected trial wedge to be
9 secured to the trial body and for holding stacked wedges together.

1 14. The surgical orthopaedic joint replacement of claim 13 wherein the
2 magnetic member includes a magnet embedded within each trial wedge.

1 15. The surgical orthopaedic joint replacement of claim 13 wherein at
2 least some of the trial wedges have opposed surfaces that define an acute angle.

1 16. The surgical orthopaedic joint replacement of claim 13 wherein the
2 trial body has a flat non-articulating surface that receives the trial wedges.

1 17. The surgical orthopaedic joint replacement of claim 13 wherein the
2 trial body has two spaced apart surfaces that enable a surgeon to attach two trial
3 wedges to the respective spaced apart surfaces, and wherein wedges can be stacked
4 upon either of the spaced apart surfaces.

1 18. The surgical orthopaedic joint replacement of claim 17 wherein each
2 of the spaced apart surfaces is generally flat.

1 19. The surgical orthopaedic joint replacement of claim 13 wherein at
2 least some of the wedges are shaped with opposed, parallel surfaces to enable one
3 to stack upon another.

1 20. The surgical orthopaedic joint replacement of claim 13 wherein the
2 trial body and at least some wedges are embossed to prevent rotation after a wedge
3 is attached to the trial body.

1 21. The surgical orthopaedic joint replacement of claim 13 wherein the
2 trial body and at least some wedges have corresponding interlocking portions.

1 22. The surgical orthopaedic joint replacement of claim 21 wherein the
2 interlocking portions comprise interlocking socket and projecting portions.

1 23. The surgical orthopaedic joint replacement of claim 13 wherein the
2 trial wedges have differing thicknesses.

1 24. The surgical orthopaedic joint replacement of claim 13 wherein the
2 trial body has an articulating surface portion for articulating with an articulating
3 surface of another orthopaedic prosthetic component.

4 25. A surgical orthopaedic hip joint replacement trial instrument
5 comprising:

6 a) a trial body having proximal and distal end portions and that
7 fits an end portion of a patients proximal femur;

8 b) a plurality of trial neck elements that removably affix to the
9 trial body, enabling a surgeon to vary the size and shape of the trial body at the
10 proximal end thereof;

11 c) at least some of the neck elements having different
12 configurations; and

13 d) a magnetic member that holds a selected neck element and the
14 trial body together.

1 26. The surgical orthopaedic hip joint replacement of claim 25 wherein
2 the magnetic member is a magnet embedded within each neck element.

1 27. The surgical orthopaedic joint replacement of claim 1 wherein the
2 trial body has a rasping surface thereon.

1 28. The surgical orthopaedic joint replacement of claim 25 wherein the
2 trial body has a flat surface that receives a selected one of the neck elements.

1 29. The surgical orthopaedic joint replacement of claim 25 wherein the
2 trial body has a projecting portion and the neck element has a socket that receives
3 the projecting portion upon assembly.

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1 30. The surgical orthopaedic joint replacement of claim 25 wherein there
2 are a plurality of trial bodies of different size and a plurality of neck elements that
3 each fit a trial body.

1 31. The surgical orthopaedic joint replacement of claim 25 wherein at
2 least some of the neck elements have a connection portion for receiving a femoral
3 head.

1 32. The surgical orthopaedic joint replacement of claim 25 wherein the
2 trial body and neck element have spaced apart interlocking portions to prevent
3 rotation once a neck element is attached to the trial body.

1 33. The surgical orthopaedic joint replacement of claim 25 wherein the
2 trial body and at least some neck elements have corresponding rectangular slot and
3 projecting interlocking portions.

1 34. The surgical orthopaedic joint replacement of claim 33 wherein the
2 interlocking portions comprise interlocking rectangular socket and rectangular
3 projecting portions.

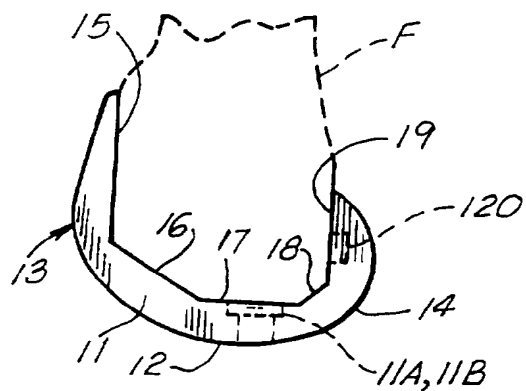


FIG. 1

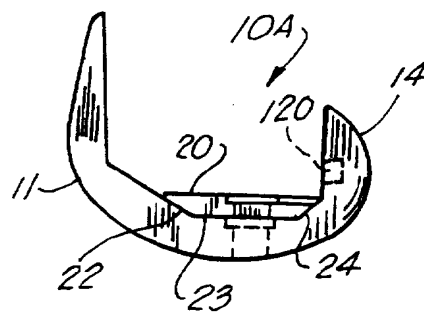


FIG. 2

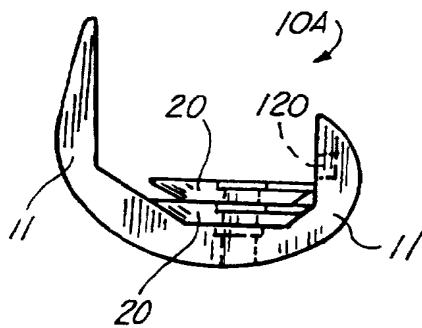


FIG. 3

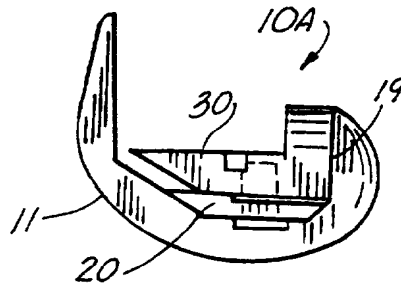


FIG. 4

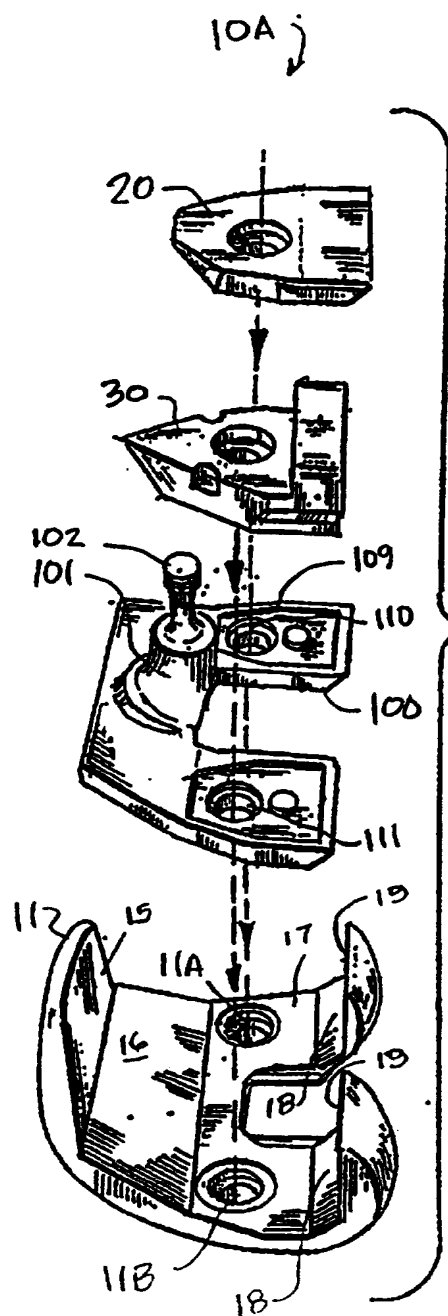


FIG. 5

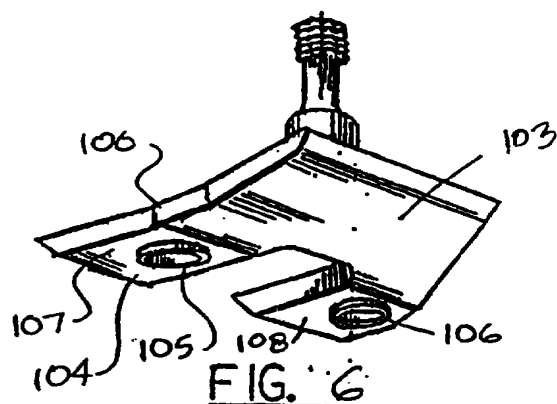


FIG. 6

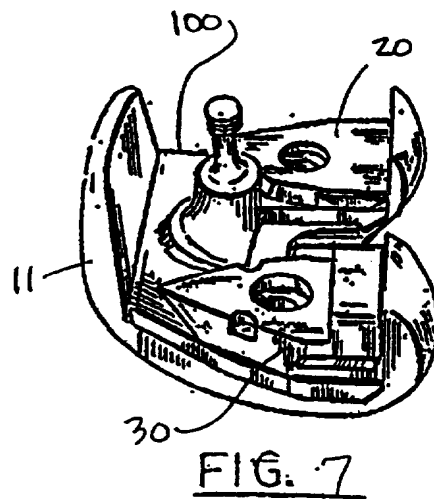


FIG. 7

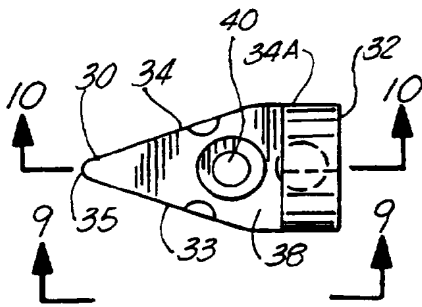


FIG. 8

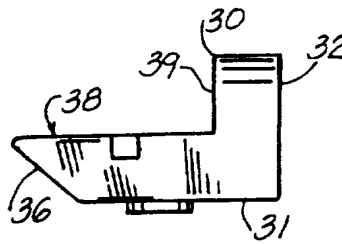


FIG. 9

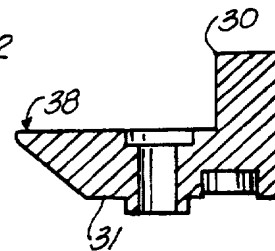


FIG. 10

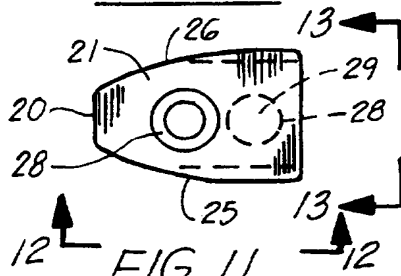


FIG. 11

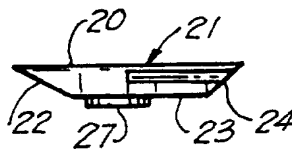


FIG. 12

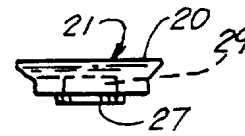


FIG. 13

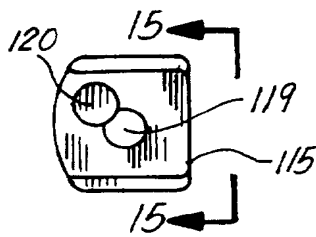


FIG. 14

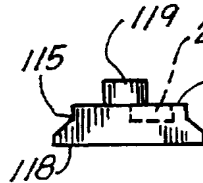


FIG. 15

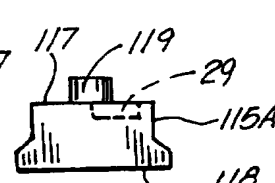


FIG. 15A

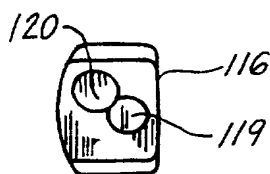


FIG. 16

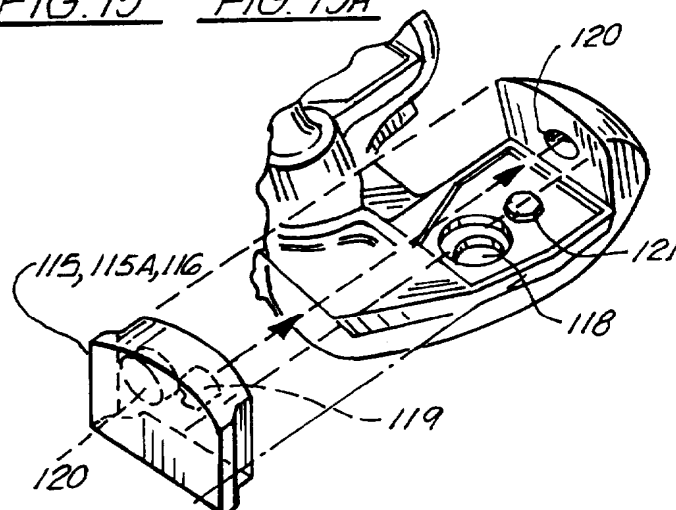
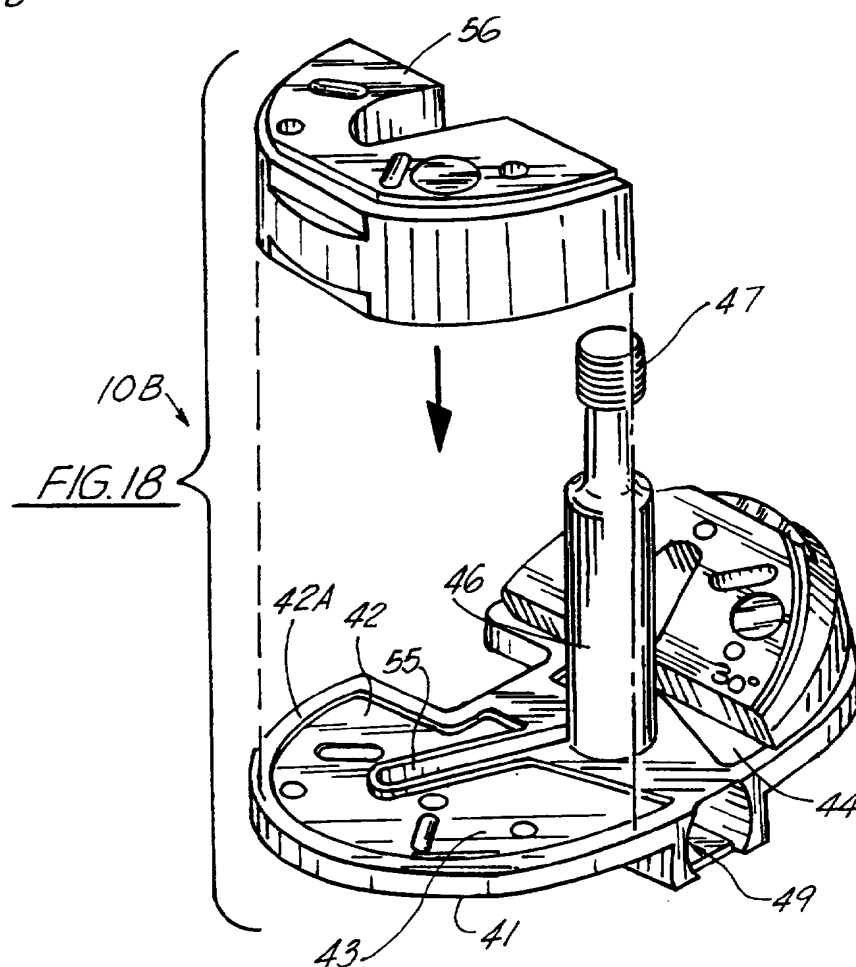
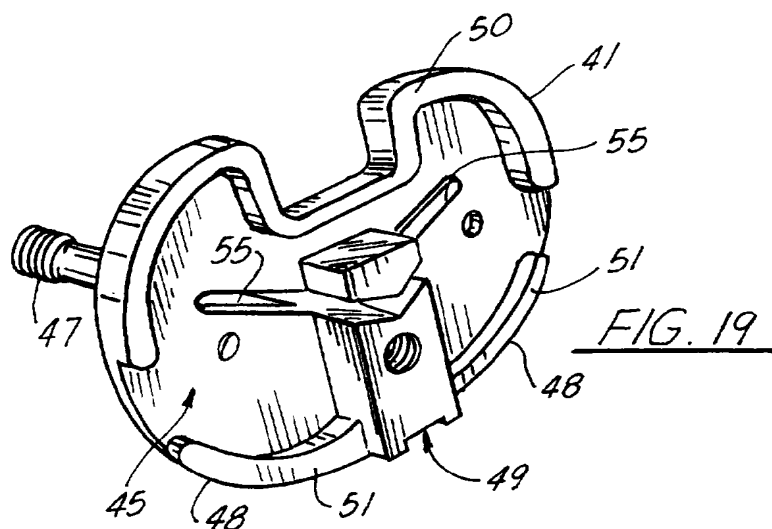
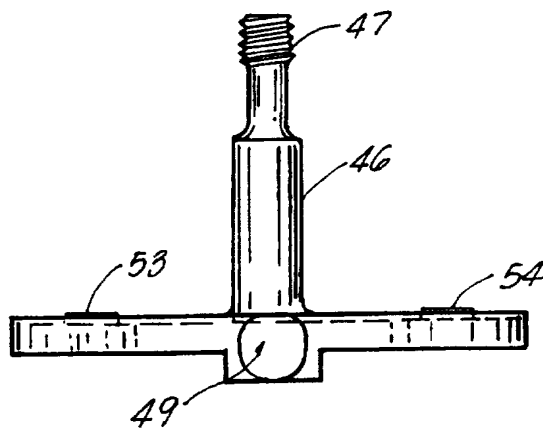
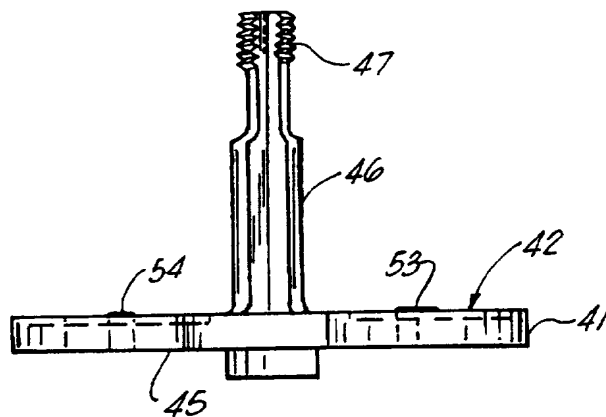
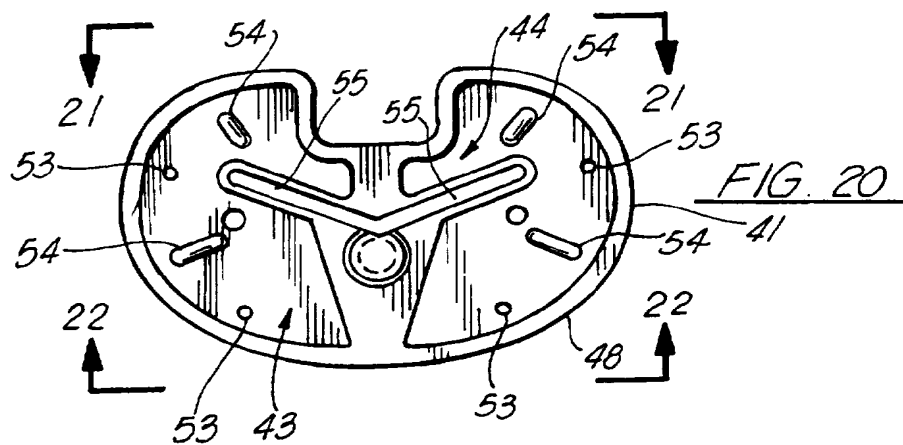


FIG. 17

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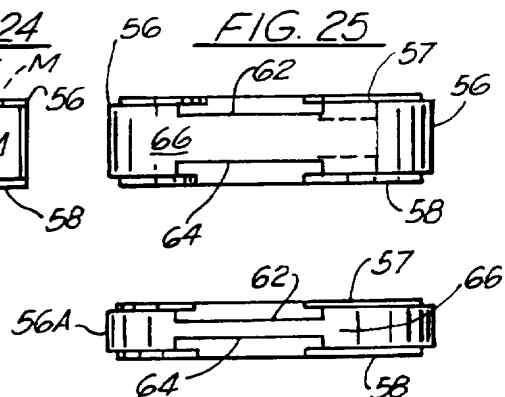
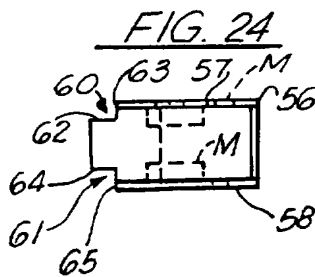
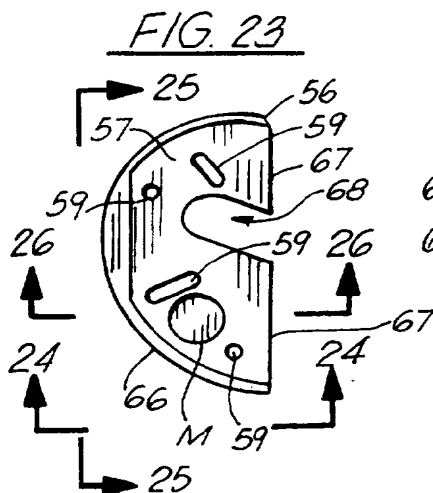


FIG. 25A

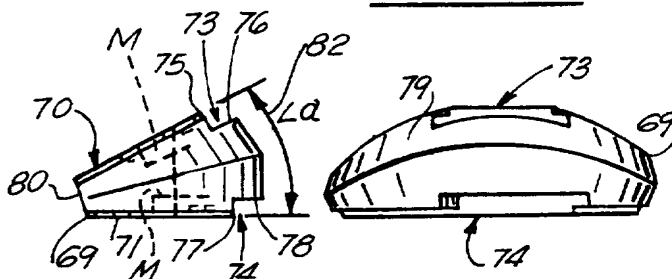
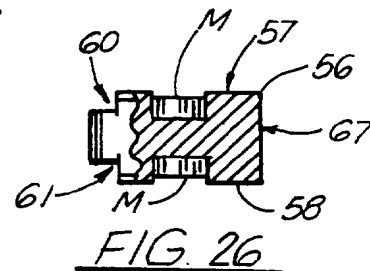
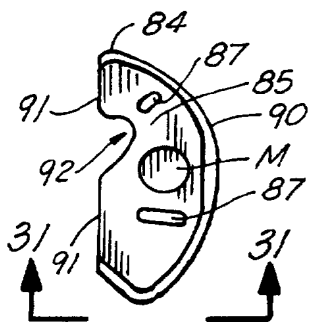
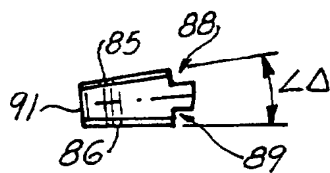
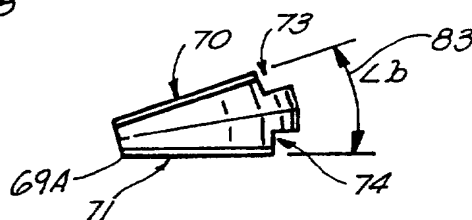
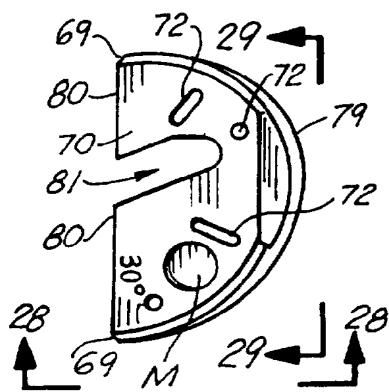


FIG. 29



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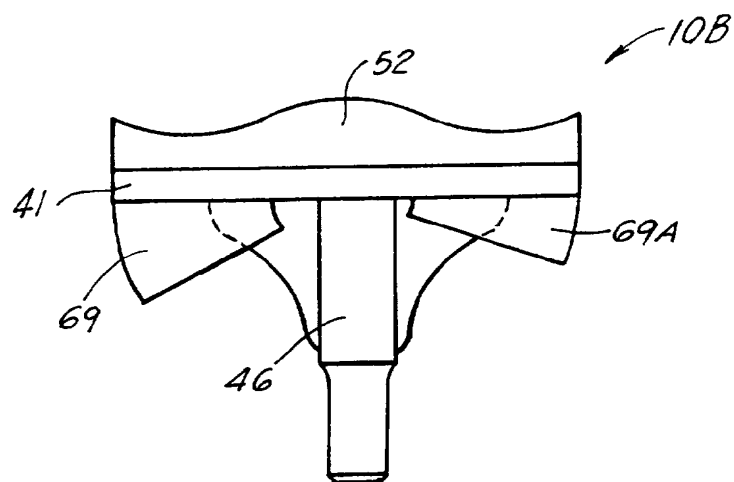


FIG. 32

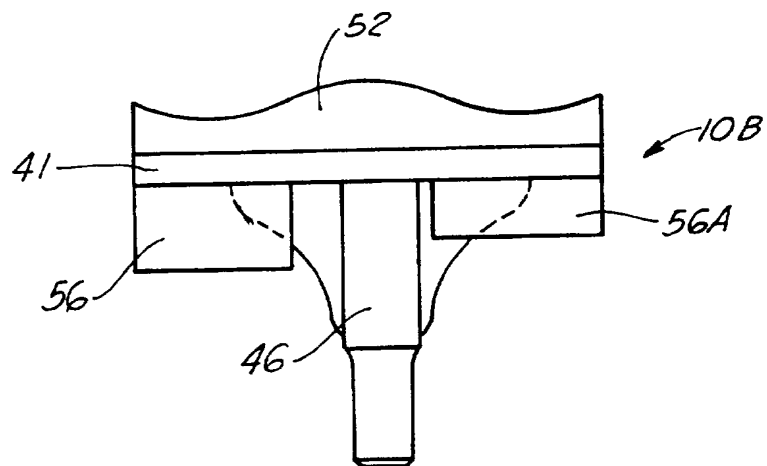


FIG. 33

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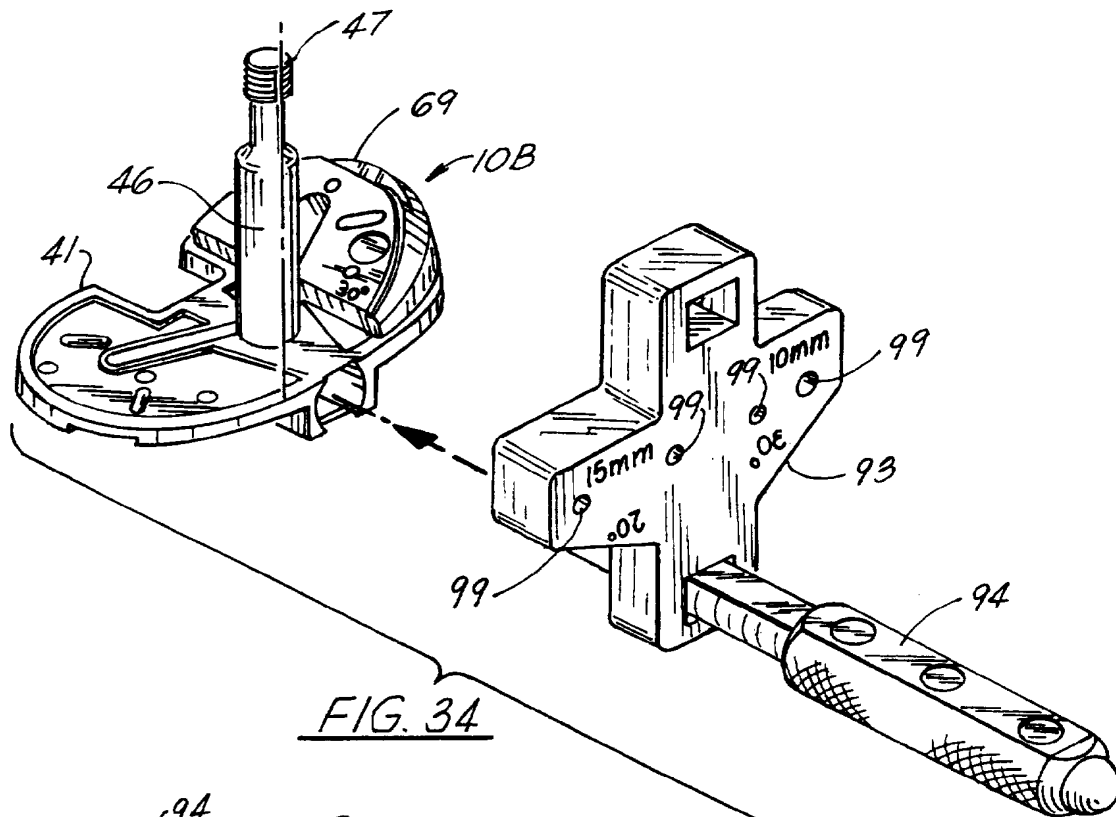


FIG. 34

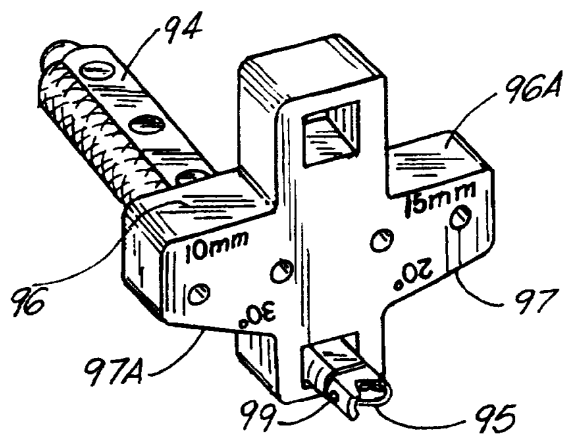


FIG. 35

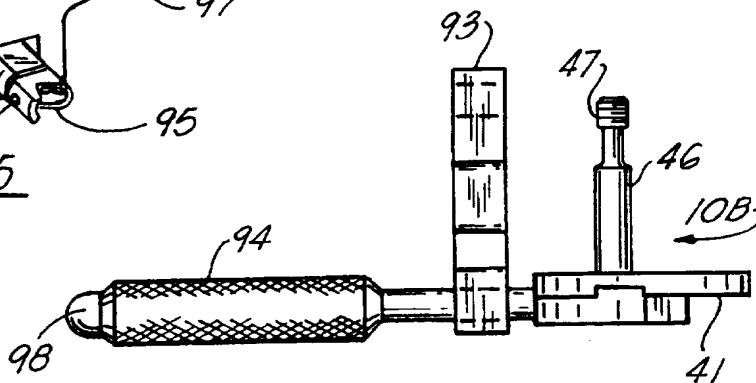
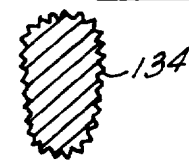
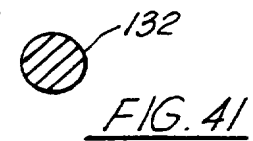
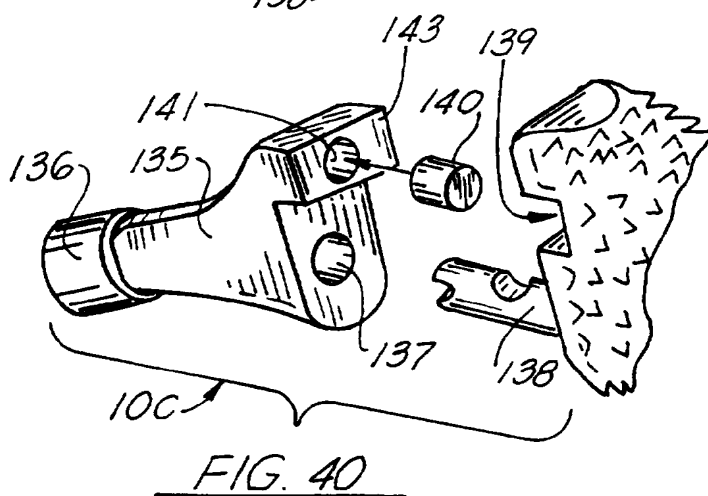
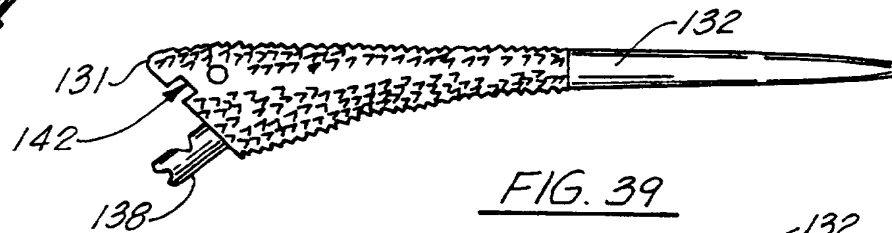
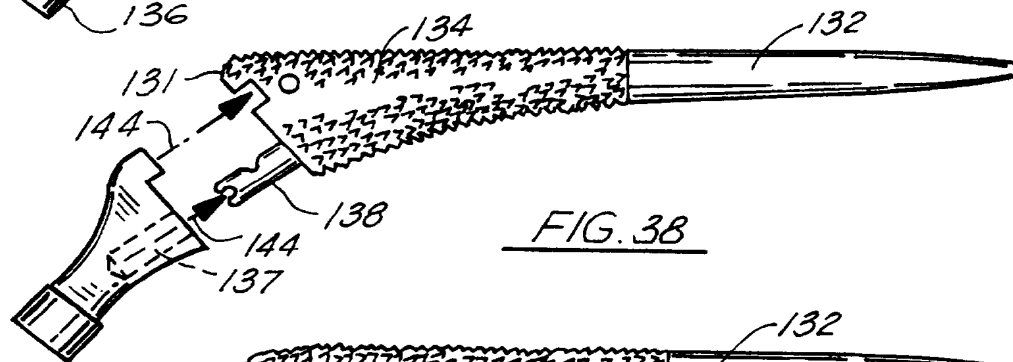
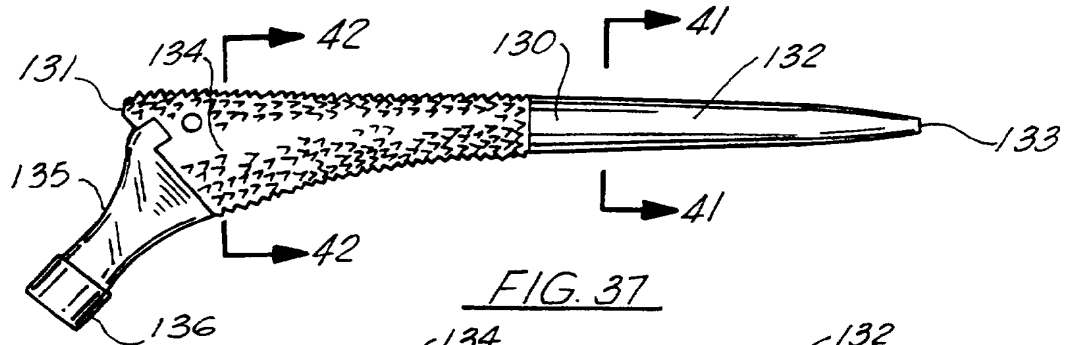
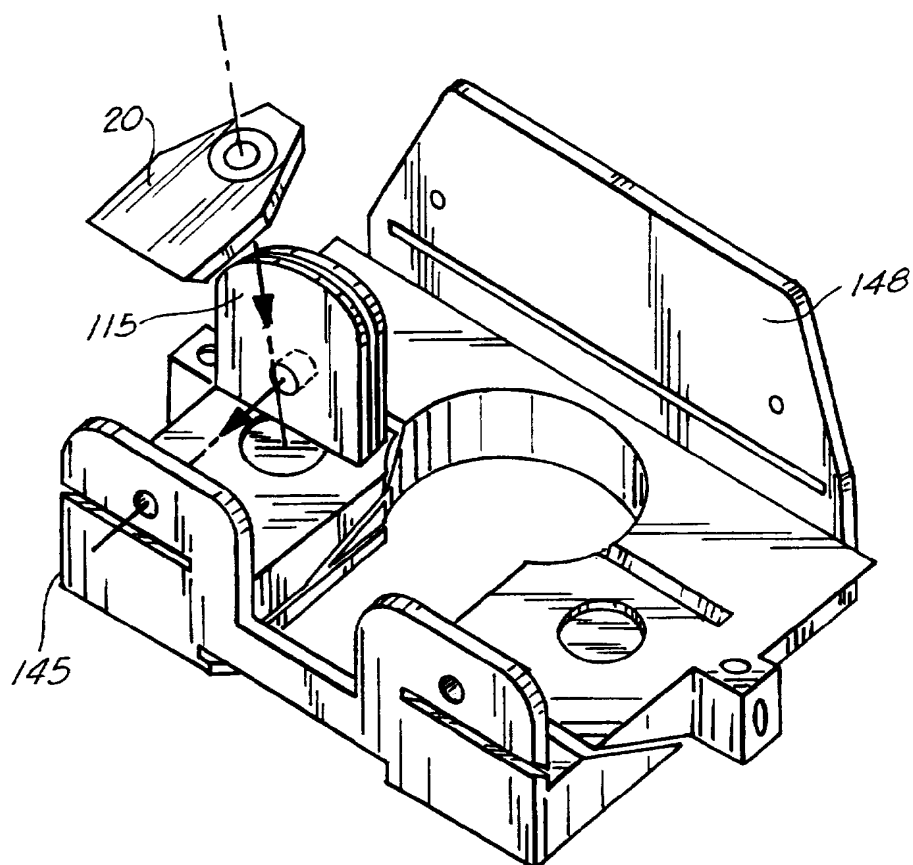
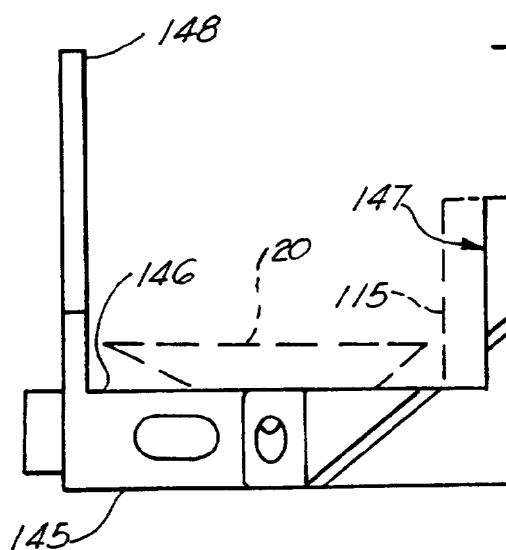


FIG. 36

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FIG. 43FIG. 44

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/02805

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/30, 36, 38

US CL : 623/18, 20, 23

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/18, 20, 23

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

Search Terms: 623/clas, 606/clas, implant, prosthesis, bone, knee, hip, femur, femoral, magnet, magnets

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,950,298 A (GUSTILO et al.) 21 August 1990, entire document.	1-24
A	US 4,936,853 A (FABIAN et al.) 26 June 1990, Fig. 5, and col. 3 line 64 to col. 4 line 7.	8-10, 20-22
A	US 5,549,706 A (McCARTHY) 27 August 1996, Figs. 1 and 2.	25-34

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

05 MAY 1997

Date of mailing of the international search report

06 JUN 1997

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Facsimile No. (703) 305-3230

Authorized officer

RANDY SHAY

Telephone No. (703) 308-2907